May 2018 | Issue Brief

How Does the Trump Administration Drug Pricing Blueprint Affect Medicaid?

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The cost of prescription drugs continues to be a policy issue for the U.S. health system and for state Medicaid programs. Recent news stories have highlighted the high costs of life-saving drugs such as Sovaldi, EpiPen, Daraprim, insulin, and oncology drugs; the American public[1] reports concern over high out-of-pocket spending for prescriptions; and many states are pursuing actions to try to lower drug costs.[2] President Trump campaigned on the issue and has since repeatedly commented that lowering the cost of prescription drugs is one of his greatest priorities. On May 11th, 2018, the Trump Administration released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" ("the Blueprint"), which reviews the issue of high cost drugs, presents actions the Administration has already taken, lists actions that the Administration may undertake or promote going forward, and seeks feedback on potential actions. The Blueprint includes provisions across the U.S. healthcare system; this issue brief focuses on how the Blueprint's proposals could affect Medicaid drug spending.

New Medicaid Proposals

The only new, Medicaid-specific proposal in the Blueprint is a technical provision related to the Medicaid Drug Rebate Program (MDRP). The Blueprint suggests that "HHS may […] [d]evelop proposals related to the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of the Average Manufacturer Price." This proposal is referring to the MDRP, which stipulates that in return for state Medicaid agency coverage of nearly all drugs produced by the manufacturer, the manufacturer must provide a rebate as described in federal Medicaid law. The amount of the federal rebate is based on both a non-inflationary component (based on whether the drug is a brand or a generic) and an inflationary component that accounts for the increase in the drug's price relative to inflation. Currently, the total rebate is capped at 100% of Average Manufacturer Price (AMP).

The Blueprint provision is based on the idea that removing or significantly increasing the rebate cap would be a disincentive for a manufacturer to increase its list price for any drug for which Medicaid collects rebates.[3] However, it would not directly affect drugs for which Medicaid does not collect rebates, such as physician-administered drugs provided on an inpatient basis. In addition, the rebate cap is currently secured in Medicaid statute[4] and would require Congressional action to be modified.

Other Proposals

The Blueprint also includes two proposals related to Medicaid drug spending that the Administration first proposed in the FY 2019 White House Budget[5]: removing ambiguity over how drugs are reported in Medicaid and calling for a new Medicaid demonstration authority for states to implement their own formularies instead of participating in the MDRP. The first proposal stems from the idea that, because the federal Medicaid rebates vary based on whether the drug is a brand or a generic, in addition to some other distinctions amongst brand drugs, for Medicaid to recoup the appropriate amount of money, the prescription drugs being provided need to be correctly categorized.[6] The second proposal calls for a new Medicaid demonstration authority limited to five states and would allow for state Medicaid agencies to create their own Medicaid formularies. The proposal is based in the idea that, in contrast to the open formulary essentially created by the MDRP, allowing states to utilize their own formularies would enable them to negotiate directly with manufacturers.[7] However, opponents worry that states would use this authority to limit or deny coverage of high-priced drugs.

Non-Medicaid Proposals

The Blueprint proposes a number of actions to address high drug costs that are broader in scope, affecting all payers including Medicaid. Over the past year, the FDA has taken a variety of actions to encourage generic competition to ease the high cost of prescription drugs. The Blueprint proposes continuing a number of ongoing FDA initiatives. It also proposes that HHS direct CMS to develop demonstration projects to encourage value-based care[8] and to make prices more transparent to the public[9].

Looking Ahead

The Trump Administration is seeking comment on the Blueprint through July 16, 2018, and the Blueprint includes many questions for policymakers and stakeholders to consider as they develop actions based on the Blueprint. These questions include direct questions about the likely effect of proposed Medicaid policies (e.g., removing the rebate cap). Notably, the questions also ask if and how low prices in Medicaid (and other government programs) may incentivize manufacturers to increase prices for drugs overall to recoup perceived lost profits. The Blueprint also asks about pricing transparency and potential alternative prescription drug payment structures in Medicaid (and Medicare) including: pricing curative drugs to account for the fact that current payers may not realize long-term cost savings from lower treatment costs; pricing drugs based on the indication they are used for and how effective the drug is for that specific indication; and pricing drugs to remove disincentives to provide a drug in a particular setting (e.g., inpatient versus outpatient).

It is unclear what policy actions will ultimately emerge from the Blueprint, and not all proposals in the Blueprint can be implemented through administrative (versus Congressional) action. However, the document provides insight into the Administration's areas of interest for lowering drug costs overall. While Medicaid-specific provisions focus on increasing manufacturer rebates, other discussion in the Blueprint suggests concern over Medicaid rebates leading to higher prices system-wide. The question of which provisions are priorities will be shaped by ongoing policy debate, politics, and stakeholder responses to the ideas in the Blueprint.

ENDNOTES

[1] "Public Opinion on Prescription Drugs and Their Prices," Kaiser Family Foundation, https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/.

[2] K Young and R Garfield, *Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control*, Kaiser Family Foundation, February 2018, https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/.

[3] Secretary Azar presented this position in his comments at the White House Press Briefing Friday, May 11th, 2018.

[4] 42 U.S.C. 1396r-8(c)

[5] FY 2019 HHS Budget in Brief, "Putting America's Health First, FY 2019 President's Budget for HHS," https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

[6] In August 2017, Mylan settled with the Department of Justice to resolve claims that they had intentionally classified the EpiPen product incorrectly as a generic drug to pay less money in rebates to Medicaid. *See* "Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates," Department of Justice, August 17, 2017, https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates. Additionally, a 2017 OIG report found that Medicaid lost over a billion dollars in rebates between 2012 and 2016 due to misclassification of drugs. *See* "Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates," HHS, Office of Inspector General, December 2017, https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf.

[7] For more information on formularies in Medicaid, *see* Young and Garfield, *op. cit*.

[8] The Blueprint strongly favors value-based pricing, at one point saying "[v]alue-based transformation of our entire healthcare system is a top HHS priority." Value-based pricing is a popular idea, and one that requires reconciling with the best price aspect of the MDRP.

[9] On May 15th 2018, CMS unveiled its "enhanced drug dashboard."